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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

ACTAVIS LLC; APOTEX, INC.; APOTEX, CORP.; BEDFORD LABORATORIES; DR. REDDY'S LABORATORIES LTD.; EMCURE PHARMACEUTICALS USA, INC.; EMCURE PHARMACEUTICS, LTD.; HOSPIRA, INC.; PHARMACEUTICS INTERNATIONAL INC.; PHARMAFORCE, INC.; SAGENT PHARMACEUTICALS, INC.; ACS DOBFAR INFO S.A.; STRIDES, INC.; AGILA SPECIALTIES PRIVATE LTD.; SUN PHARMACEUTICALS INDUSTRIES, INC.; SUN PHARMA GLOBAL FZE; CARACO PHARMACEUTICAL LABORATORIES, LTD.; SUN PHARMACEUTICAL INDUSTRIES LTD.; TEVA PARENTERAL MEDICINES, INC.; WOCKHARDT USA LLC; and WOCKHARDT LTD.,

Defendants.

Civ. Action No. 13-1028 (SDW) (MCA)

(Filed Electronically)

SAGENT'S OPPOSITION TO NOVARTIS'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION

PUBLIC VERSION

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Defendants Sagent Pharmaceuticals, Inc. and ACS Dobfar Info S.A. (collectively, "Sagent") respectfully submit this opposition to Novartis' Opening Brief in Support of its Motion for a Temporary Restraining Order and a Preliminary Injunction ("Novartis' Brief").

Sagent adopts and incorporates by reference the opposition submissions of the co-defendants concerning invalidity of U.S. Patent Nos. 8,324,189 ("the '189 patent") and 8,052,987 ("the '987 patent"). Sagent submits this opposition to present further arguments that Sagent's generic Reclast® product does not induce infringement of, and does not contribute to infringement of, the '987 patent; that any temporary restraining order which may issue against Sagent should by its terms automatically dissolve in the event of a launch by another defendant, or in the event of a generic launch authorized or licensed by Novartis; that Novartis' requested temporary restraining order would not maintain the status quo; that Novartis' motion should be denied because Novartis unduly delayed its present application for relief; and to establish the amount of Novartis' bond in the event this Court grants Novartis' application for a temporary restraining order.

A. <u>Non-Infringement of the '987 Patent</u>

1. *No Contributory Infringement*

REDACTED

(Novartis Brief at pp. 9, 21). Yet, on a website[1] apparently endorsed by Novartis, it is represented that about 2 percent of people in the U.S. who are over 55 years old have Paget's disease, about 10 percent of people in the U.S. who are over 80 year old have Paget's disease, and about 2 million people in the U.S.

[1] Http://www.freemd.com/pagets-disease/incidence.htm.

have Paget's disease. *See* Declaration of Marilyn Neiman ("Neiman Decl."), Exhibit C. REDACTED

REDACTED

Novartis contends that REDACTED

(Novartis Brief, p. 21). Yet when Novartis first developed and obtained approval for Reclast® – at a cost much, much greater than the cost of a bringing a generic to market – it was marketed solely for Paget's disease. *See* Neiman Decl., Exhibit B, Novartis' April 2007 label for Reclast® at page 5 which shows treatment of Paget's Disease of the Bone as the sole indicated use.

Even applying REDACTED treatment

REDACTED

Novartis' representation REDACTED

(Novartis Brief at p. 9) may be reflective of Novartis' failure to effectively market Reclast® for Paget's disease rather than the true size of that market segment.

REDACTED

See Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1327 (Fed. Cir. 2009) ("[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental."); *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010), *aff'd*, 131 S.Ct. 2238 (2011)

(substantiality determination is not based only on frequency of the alternative use, "but also the use's practicality, the invention's intended purpose, and the intended market").

2. *No Inducement of Infringement*

REDACTED

REDACTED

Upon approval, Sagent will not advertise, market, or otherwise promote its general Reclast® product for any indication not on Sagent's label for its generic Reclast® product. *See* Declaration of Victoria Wohlfeil ("Wohlfeil Decl."). In short, there is no evidence that Sagent "has or will promote or encourage doctors to infringe" the '987 patent, and as the Federal Circuit has explained, "[m]ere knowledge of possible infringement by others does not amount to inducement; specific intent *and* action to induce infringement must be proven." *Warner Lambert v. Apotex*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (*emphasis added*).

REDACTED

"[n]othing in the [Hatch-Waxman] Act requires that an ANDA must encompass *every* approved indication." *Astrazeneca v. Apotex*, 669 F.3d 1370, 1379 (Fed. Cir. 2012). REDACTED

cannot be vitiated by purported market realities, i.e., automatic substitution for other indications over which Sagent has no control:

> AstraZeneca also argues that Section viii statements and restricted generic labeling ignore market realities because even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available. We find this argument unpersuasive. First, AstraZeneca's position would, in practice, vitiate § 355(j)(2)(A)(viii) by enabling § 271(e)(2) infringement claims despite the fact that Appellees' Section viii statements and corresponding proposed labeling explicitly and undisputedly carve out all patented indications for rosuvastatin calcium. Moreover, if accepted, these speculative arguments would allow a pioneer drug manufacturer to maintain de facto indefinite exclusivity over

> a pharmaceutical compound by obtaining serial patents for approved methods of using the compound and then wielding § 271(e)(2) 'as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be barred altogether from entering the market.' *Warner-Lambert*, 316 F.3d at 1359. We cannot agree with this expansive view of § 271(e)(2), which is contrary to the statutory scheme.

Astrazeneca, 669 F.3d at 1380.

B. <u>No Irreparable Injury if Another Generic is Permitted to Launch</u>

REDACTED

In the event this Court agrees that Wockhardt should not be temporarily enjoined, or, for that matter, that any other generic should not be temporarily enjoined, and Wockhardt or such other generic launches a generic Reclast® or Zometa® product, then

REDACTED

See, *e.g.*, Novartis' Declarations of Lisa Deschamps, paragraph 15; Novartis Brief at p. 27. The same situation would apply if Novartis itself authorizes or licenses the launch of a generic version of Zometa® or Reclast®.

Accordingly, Sagent respectfully submits that any temporary restraining order issued as against Sagent should by its terms automatically dissolve upon a launch by any generic company of a generic version of Zometa® or Reclast®.

[2] Of course, if Novartis ultimately prevails against such generic companies, it will be entitled to seek damages for zoledronic acid products sold by them.

C. Novartis' Requested Temporary Restraining Order Would Not Maintain the Status Quo

Through advertisements on the internet, Novartis has advertised the availability of generic zoledronic in March 2013. Novartis has been using these advertisements to solicit patients to purchase Novartis' Zometa® now, with the expectation that they may be able to continue on a less expensive generic zoledronic acid after the March 2, 2013, expiration of Novartis' U.S. Patent No. 4,939,130 that covers the zoledronic acid molecule. *See* Neiman Decl., Exhibits C-H. These advertisements include the statements that "the ZOMETA® patent will expire in March 2013"; encourage patients to "talk to your doctor about ZOMETA® today, as you may be able to continue on generic zoledronic acid after the ZOMETA® patent expires in March 2013"; and advises the public that "[l]ower co-pays and co-insurance may be available to you" with generic zoledronic acid. *Id.*

As is evident, Novartis has embarked on a marketing effort to increase its sales of Zometa® by advertising that a less expensive generic zoledronic acid will be available in March 2013. Having made these representations to the public and having used the introduction of generic zoledronic acid into the market in March 2013 to increase its sales of Zometa®, Novartis cannot now be heard to complain that the expectation of generic entry in March 2013 will become a reality. As such, entry of a restraining order, rather than preserving the status quo, would be directly contrary to the expectations created by Novartis' own self-interested advertising campaign.

D. Novartis' Delay also Mandates Denial of its Motion for Temporary Restraining Order

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Indeed, Novartis delayed until February 21, 2013, to file its Complaint in this action. While Novartis may have been entitled to delay its lawsuit, equity does not reward a dilatory plaintiff with the exceptional relief of a temporary restraining order when the issues could have been raised and resolved much earlier. *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) ("The district court correctly noted that [two year] delay in bringing an infringement action and seeking a preliminary injunction are factors that could suggest that the patentee is not irreparably harmed by the infringement"); *Nutrition 21 v. United States*, 930 F.2d 867, 872 (Fed. Cir. 1991) ("that Nutrition 21 delayed for a substantial period of time before seeking a preliminary injunction at least suggests that the status quo does not irreparably damage Nutrition 21. Therefore, if there is a basis for finding irreparable harm, the court's findings fail to factually support it"); *Graceway Pharms., LLC v. Perrigo Co.*, 697 F. Supp. 2d 600, 610 (D. N.J. 2010).

Accordingly, for the additional reason that Novartis unduly delayed in filing the present application for relief, its motion for a temporary restraining order and preliminary injunction should be denied.

E. BOND

But for the issuance of a temporary restraining order by the Court, Sagent would be positioned to launch its generic Zometa® and Reclast® products upon the March 2, 2013, expiration of Novartis' '130 patent. *See* Wohlfeil Decl.

Rule 65(c) of the Federal Rules of Civil Procedure provides:

> **Security**. The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by an party found to have been wrongfully enjoined or restrained.

The amount of the bond is the limit of recovery for a party wrongfully enjoined. Instant *Air Freight Co. v. C.F. Air Freight, Inc*., 882 F.2d 797, 804 n.9 (3d Cir. 1989) ("[t]he rule limiting liability to the amount of the bond provides the plaintiff with notice of the maximum extent of her liability. The bond can thus be seen as a contract in which the court and plaintiff 'agree' to the bond amount as the 'price' of a wrongful injunction."). Therefore, the bond should be set high enough to insure that the enjoined party is fully compensated in the event the injunction is ultimately dissolved. REDACTED

See Wohlfeil Decl.

F. Conclusion

For the foregoing reasons, Novartis' motion for a temporary restraining order should be denied, and a briefing schedule on Novartis' motion for a preliminary injunction should be

ordered. If a temporary restraining order is granted, Novartis should be required to post a bond in the amount of at least REDACTED

Dated: New York, New York
February 28, 2013

COZEN O'CONNOR

s/ Marilyn Neiman

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CERTIFICATE OF SERVICE

I hereby certify that on February 28, 2013, I caused this OPPOSITION TO NOVARTIS'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION to be filed with the Court under Seal and served upon all counsel of record via ECF and by email to all counsel of record on a "Confidential Outside Attorneys Eyes Only" basis.

s/ Marilyn Neiman
Marilyn Neiman